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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,412	12/26/2006	Hilmar Bischoff	BHC 031059	1665
35969	7590	06/03/2010	EXAMINER	
Barbara A. Shimek			GEMBEH, SHIRLEY V	
Director, Patents & Licensing			ART UNIT	PAPER NUMBER
Bayer HealthCare LLC - Pharmaceuticals				
555 White Plains Road, Third Floor			1618	
Tarrytown, NY 10591				
MAIL DATE		DELIVERY MODE		
06/03/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/578,412	BISCHOFF ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 April 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3 and 6-26 is/are pending in the application.  
 4a) Of the above claim(s) 12-22 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3,6-11 and 23-26 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-3 and 6-26 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election of Group I (claims 1-3, 6-11 and 23-38) in the reply filed on April 29, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 12-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

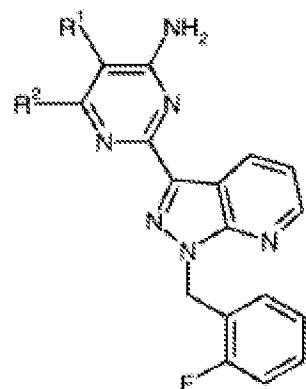
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-11 and 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bischoff et al. ((US 2004/0186163) having priority date of 8/17/01) in view of Alonso-Aluja et al. (US Patent 7,173,037).

Bischoff et al. teach a combination product which comprises a pharmaceutically active ingredient of component A (a soluble guanylate cyclase stimulator and a lipid lowering agent; see abstract as required by instant claims 1-2) wherein the soluble



guanylate cyclase stimulator is a compound

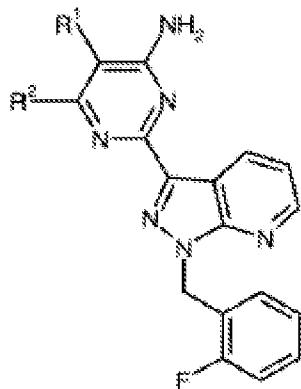
Recited compound of Formula I (instant claim)	Prior Art compound	SAME
$R^1 NR^3(=O)OR^4$	$R^i$ differs (see para. 0108)	differs
$R^2$	$R^{ii}$	Hydrogen or $NH_2$

Bischoff also teaches that components A and B are in the form of a functional unit (see page abstract and para 0014, as required by instant claim 6) separate in a kit

(as required by instant claim 7, see 0014 and 0016). Bischoff further teaches that the lipid lowering agent is selected from HMG-CoA reductase inhibitors (i.e., statins) wherein the statins may be atorvastatin, cerivastatin (as required by instant claims 8-11 and 26 see para. 0022 and 0034-0046) in their respective salts hydrates and tautomers (as required by instant claims 10-11). Additionally Bischoff teaches the combination product may be separately administered either simultaneously or sequentially (as required by instant claims 24-25, see para. 0016 and 0017).

However Bischoff fails to teach the compound has the same substituent of  $R^1$  (i.e.  $R^1$  as recited in the instant claim).

Alonso-Aluja et al. teach a composition comprising a pharmaceutical active ingredient component A that is a direct stimulator of soluble guanylate cyclase having the same chemical structure as the recited formula I (see abstract), wherein



Recited compound of Formula I	Prior Art compound	SAME
$R^1$	$R^1$	$NR^3(=O)OR^4$
$R^2$	$R^2$	Hydrogen or $NH_2$

$R^3$	$R^3$	(C1-C4)-alkyl
$R^4$	$R^4$	(C1-C6)-alkyl

as required by instant claims 1-3 (see col. 2, lines 23-65 and col. 3, lines 1-23 (as required by instant claim 3). The composition of Alonso includes other active agents to be administered in combination with the compounds of formula I for use as medicaments for the treatment of cardiovascular disorders, such as high blood pressure, atherosclerosis (i.e., conditions in which fatty material collects along the walls of arteries, see col. 8, lines 56-65) and which includes nitric oxide donors (which releases nitric oxide in treatment, see col. 9, lines 45-55).

Intrinsically the compound/composition of formula 1 (component A) may be "permitted" to be administered separately, simultaneously with the NO donor compound or sequentially (as required by instant claims 24-25).

However Alonso-Alija et al. fail to teach that the active ingredient of component B is a HMG-CoA inhibitor (i.e., atorvastatin, cerivastatin; as required by instant claims 1, 8-11 and 26).

One of ordinary skill in the art would have been motivated to substitute the compound of Bischoff with the compound of Alonso-Alija with a reasonable expectation of success because both compounds are known as "a direct soluble guanylate cyclase stimulator". Therefore substituting one for another would reasonable result in an expectation of success from the knowledge that members of the same class will behave in the same way in the context of the claimed invention. In other words, each member

could be substituted one for the other, with the expectation that the same intended result would be achieved.

Thus, the claimed invention was *prima facie* obvious.

3. No claim is allowed.

4. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./  
Examiner, Art Unit 1618  
5/29/10

/Robert C. Hayes/  
Primary Examiner, Art Unit 1649